a CooperSurgical Company

K133387

APR 2 9 2014

510(K) SUMMARY

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

Submitted by: ORIGIO a/s
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Contact person: Tove Kjær
Director Corporate Regulatory Affairs
ORIGIO a/s

Date Submitted: April 11, 2014

Device Identification
Trade Name: ORIGIO® Sequential Blast™
ORIGIO® Sequential Blast™ with phenol red

Common name: ORIGIO® Sequential Blast™

Classification Name: Reproductive media and supplements (21 CFR 884.6180, Product Code MQL)

Predicate Device
ORIGIO a/s BlastAssist® (K080172)

Description
ORIGIO® Sequential Blast™ (with and without phenol red) is intended for the culture of human embryos from the 4-8 cell stage through to the blastocyst stage and for embryo transfer.

Two versions of ORIGIO® Sequential Blast™ are available:

- Catalogue no. 8305: ORIGIO® Sequential Blast™
- Catalogue no. 8306: ORIGIO® Sequential Blast™ with phenol red

Both versions of ORIGIO® Sequential Blast™ are aseptically filtered, non viscous solutions, light pink or colorless solutions, which are ready to use by professionals within assisted reproduction.

The ORIGIO® Sequential Blast™ media are contained in 10 mL or 60 mL transparent polyethylene terephthalate glycol (PETG) bottles with high density polyethylene (HDPE) closures, available in card board boxes of 1 x 10 mL and 1 x 60 mL bottles. The bottles and boxes are individually labeled. The boxes also contain instruction for use provided as package insert.

Indication for use

ORIGIO® Sequential Blast™ is for the culture of embryos from the 4-8 cell stage through to the blastocyst stage.

ORIGIO® Sequential Blast™ can also be used for embryo transfer.

Technological Characteristics

The design of ORIGIO® Sequential Blast™ as well as the predicate listed in this submission is based on each medium containing the appropriate nutrients for the embryo development stage it is intended for. Table 1 compares the technological characteristics of ORIGIO® Sequential Blast™ to the predicate BlastAssist®. Both similarities and differences are illustrated.

ORIGIO® Sequential Blast™ is for culture and transfer of embryos as the predicate BlastAssist®. Thus, the intended use of ORIGIO® Sequential Blast™ is considered identical to the predicate.

Table 1. Comparison of ORIGIO® Sequential Blast™ with the predicate.

Product	**ORIGIO® Sequential Blast™**	**BlastAssist®**
Indication for use	ORIGIO® Sequential Blast™ is for the culture of embryos from the 4-8 cell stage through to the blastocyst stage. ORIGIO® Sequential Blast™ can also be used for embryo transfer.	BlastAssist® is for culture from the 4-8 cell stage through to blastocyst stage. Can also be used for embryo transfer.
Product specification		
pH	7.2-7.5	7.3-7.5
Osmolality (mOsm/kg)	272-288	272-288
Endotoxin (EU/mL)	<0.15	≤0.1
Sterility	No growth	No growth
1-cell MEA	≥80%	≥80%
Formulation		
Physiological salts	Magnesium sulphate Potassium sulphate Sodium chloride Sodium dihydrogen phosphate	Magnesium sulphate Potassium sulphate Sodium chloride Sodium dihydrogen phosphate
Amino acids	X	X
Stable form of L-glutamine	N-Alanyl-L-glutamine	N-Acetyl-L-glutamine
Energy sources	Glucose Calcium-L-lactate Sodium pyruvate	Glucose Calcium-L-lactate Sodium pyruvate
SSR®	X	X
Buffer	Sodium Bicarbonate	Sodium Bicarbonate

Product	ORIGIO® Sequential Blast™	BlastAssist®
Vitamins	X	X
Sodium hyaluronate	X	
Protein source		
HSA (Protein composition: > 96% albumin)	5 mg/mL	2 mg/mL
Antibiotics		
Gentamicin sulphate	10 µg/mL	10 µg/mL

The technological characteristics of ORIGIO® Sequential Blast™ are comparable to those of the predicate device. The main differences are:

- Human Serum Albumin: The majority of commercially available culture media have an HSA concentration of 5 mg/mL e.g. Universal IVF Medium (K K991279) and G-2™v5 (K081117).
- Sodium hyaluronate: ORIGIO® Sequential Blast™ contains hyaluronate in a concentration range similar to that added in other ART media products e.g. G-2™v5 (K081117).
- Stable L-glutamine: Both ORIGIO® Sequential Cleav™ and the predicate contain a stable form of glutamine. Both alanyl-glutamine used in ORIGIO® Sequential Blast™ and acetyl-glutamine used in the predicate are widely used in ART media and have a history of safe use.

The differences in composition do not impact the substantial equivalence and do not raise any new types of safety or effectiveness concern.

Performance data
The product specifications for ORIGIO® Sequential Blast™ and the predicate are similar regarding sterility, osmolality, pH, endotoxin level and Mouse Embryo Assay (MEA) test.

The shelf life of ORIGIO® Sequential Blast™ has been validated in stability studies to 36 weeks. The parameters which have been tested in the stability studies through shelf life includes pH, osmolality, endotoxin, HSA concentration, MEA, and sterility.

In general, ORIGIO® Sequential Blast™ is subject to the same control methods and, to a significant degree, contains the same components as the predicate device. ORIGIO® Sequential Blast™ has similar handling procedures and storage conditions. Therefore, ORIGIO® Sequential Blast™ is considered substantially equivalent to the predicate device BlastAssist® (K080172).

Biocompatibility
ORIGIO® Sequential Blast™ is categorized as a medium in direct contact with embryos from the 4-8 cell stage through to the blastocyst stage. Since ORIGIO® Sequential Blast™ can also be used for embryo transfer, it is also in direct contact with the uterus (patient). The biological safety evaluation (ISO 10993-1) demonstrates that ORIGIO® Sequential Blast™ consists of well tested components and is non-toxic in use. ORIGIO® Sequential Blast™ is therefore considered safe for culture of human embryos as well as transfer of embryos into the patient (uterus).

Conclusion

The conclusion from the performance and safety data, intended use comparison, product formulation comparison and test specification comparison, demonstrates that ORIGIO® Sequential Blast™ (with and without phenol red) is suitable for the intended use, and meets the criteria in the comparison to the predicate device (BlastAssist®, K080172) in which substantial equivalence has been demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2014

ORIGIO a/s
Tove Kjaer
Director Corporate Regulatory Affairs
Knardrupvej 2
Måløv 2760
Denmark

Re: K133387
Trade/Device Name: ORIGIO® Sequential Blast™ and
ORIGIO® Sequential Blast™ with phenol red
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: March 14, 2014
Received: March 31, 2014

Dear Tove Kjaer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133387

Device Name
ORIGIO® Sequential Blast™ and ORIGIO® Sequential Blast™ with phenol red

Indications for Use *(Describe)*
ORIGIO® Sequential Blast™ is for the culture of embryos from the 4-8 cell stage through to the blastocyst stage.
ORIGIO® Sequential Blast™ can also be used for embryo transfer.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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